Complete Summary

GUIDELINE TITLE

Urinary incontinence: guide to diagnosis and management.

BIBLIOGRAPHIC SOURCE(S)

Bengtson J, Chapin MD, Kohli N, Loughlin KR, Seligson J, Gharib S. Urinary incontinence: guide to diagnosis and management. Boston (MA): Brigham and Women's Hospital; 2004. 9 p. [16 references]

GUIDELINE STATUS

This is the current release of the guideline.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

On October 17, 2005, Eli Lilly and the U.S. Food and Drug Administration (FDA) notified healthcare professionals of revision to the PRECAUTIONS/Hepatotoxicity section of the prescribing information for Cymbalta (duloxetine hydrochloride), indicated for treatment of major depressive disorder and diabetic peripheral neuropathic pain. Postmarketing reports of hepatic injury (including hepatitis and cholestatic jaundice) suggest that patients with preexisting liver disease who take duloxetine may have an increased risk for further liver damage. The new labeling extends the Precaution against using Cymbalta in patients with substantial alcohol use to include those patients with chronic liver disease. It is recommended that Cymbalta not be administered to patients with any hepatic insufficiency. See the FDA Web site for more information.

COMPLETE SUMMARY CONTENT

** REGULATORY ALERT **

SCOPE

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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES IDENTIFYING INFORMATION AND AVAILABILITY DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Urinary incontinence, including

- Urge incontinence
- Overflow incontinence
- Stress incontinence
- Mixed stress and urge incontinence

GUIDELINE CATEGORY

Diagnosis Evaluation Management Treatment

CLINICAL SPECIALTY

Family Practice
Geriatrics
Internal Medicine
Obstetrics and Gynecology
Urology

INTENDED USERS

Advanced Practice Nurses Health Care Providers Physician Assistants Physicians

GUIDELINE OBJECTIVE(S)

To provide recommendations on diagnosis and management of urinary incontinence in women

TARGET POPULATION

All women with urinary incontinence

INTERVENTIONS AND PRACTICES CONSIDERED

Evaluation/Diagnosis

- 1. Patient history
- 2. Physical examination
- 3. Consider differential diagnoses/other causes
- 4. Diagnostic testing including:
 - Use of a voiding diary
 - Post-void residual (PVR) measurement
 - Urodynamic testing
 - Cystometry
 - Uroflowmetry
 - Ureteral pressure profile

Treatment/Management

- 1. Non-pharmacological treatments involving patient education/training regarding:
 - Adjustment of urine output
 - Urge suppression training
 - Bladder retraining
 - Prompted voiding
 - Discontinuation of medications that decrease detrusor contractility
 - Clean catheterizations
 - Double voiding
 - Valsalva maneuver
 - Urethral compression
 - Kegel exercises (pelvic muscle exercises)
 - Pessary use
- 2. Surgical treatments
 - Bladder neck (retropubic) suspension procedures
 - Sling procedures
 - Minimally invasive needle vaginal suspensions
- 3. Pharmacological treatments
 - Oxybutynin (Ditropan®, Ditropan XL®)
 - Tolterodine (Detrol®, Detrol LA®)
 - Propantheline
 - Dicyclomine
 - Tricyclic antidepressants (imipramine)
 - Estrogen cream
 - Estrogen-containing ring (Estring®, FemRing®)
 - Pseudoephedrine
 - Duloxetine (Not yet United States Food and Drug Administration [FDA] approved)

MAJOR OUTCOMES CONSIDERED

- · Sensitivity and specificity of diagnostic testing
- Incidence of urinary incontinence
- Urinary output volume
- Interval time between urinary voiding
- Urge to urinate

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Subjective Review

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

These guideline recommendations were reviewed by the Women's Health Guidelines Editorial Review Board.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Approach to the Patient with Urinary Incontinence

Step 1: Screen: "Do you ever lose control of your urine and wet yourself?" (NOT: Are you incontinent?).

Step 2: Perform history and physical.

History	 Duration of symptoms Frequency, volume, and timing of incontinence Precipitants to incontinence (sneezing, coughing, caffeine, alcohol, exercise, sound of water) Pregnancy history and mode of delivery Past surgeries Sexual function Bowel function-history of constipation, fecal incontinence Social and personal impact (on work, family, sexual function) Medications History of prolapse
Physical exam	 Note presence of vaginal atrophy Cystocele Have patient cough with speculum in place. Look at movement of urethra, as an assessment of pelvic support (should not move very much if good support). If urethra is prolapsed beyond introitus, refer to urologist or urogynecologist. Direct observation of urine loss using cough stress test Neurologic exam: Cognitive function, Babinski, test of peripheral nerves

Step 3: Look for potential treatable causes of incontinence. "DIAPPERS" acronym.

Delirium	Look for metabolic, infectious, neurologic causes.		
Infection	Treat underlying infection.		
Atrophic urethritis/vaginitis	Treat with topical estrogens.		
Pharmaceuticals	Consider stopping or substituting if appropriate-		
	 Drugs causing urinary retention <u>+</u> urinary frequency Alpha-adrenergic agonists (phenylpropanolamine, Sudafed) 		
	 Anticholinergic medications (tricyclic antidepressants, antipsychotics, older 		

	antihistamines, Cogentin/Artane, disopyramide, antidiarrheals [e.g., Lomotil]) Opiates Drugs causing stress incontinence Alpha blockers (e.g., prazosin, terazosin, doxazosin) Angiotensin-converting enzyme (ACE) inhibitors (if they induce cough) Loop diuretics (and alcohol), if they overwhelm ability to get to the bathroom in time		
Psychological	Severe depressionrare		
Excess excretion	Heart failure, diabetes, peripheral edema, diuretic use, excess intake		
Restricted mobility	Use commode or urinal; adjust fluid excretion		
Stool impaction	Treat appropriately		

Step 4: Exclude serious underlying causes/consequences.

- Treatable neurologic lesions (e.g., disc, brain/cord tumor, conus medullaris lesion)
- Lower urinary tract lesion (e.g., cancer of the bladder or bladder stone)
 - Check urinalysis for hematuria
 - Check urine cytology

Step 5: Determine lower urinary tract cause and treat accordingly.

Diagnostic Testing

Voiding Diary

Consider giving a voiding diary and a urine measurement container to patients at the first visit if they have symptoms consistent with urge incontinence, or if the type of incontinence is unclear. At the follow-up visit, calculate the total daily urine excretion, as well as daytime and nighttime urinary volumes. (See original guideline document for a voiding record and patient information.)

In interpreting the voiding record, consider the following:

- Large volume losses (incontinent episodes) suggest urge incontinence.
- Increased daily urinary volume can contribute to urgency, frequency, and incontinence. Adjust output to 1 to 1.5 L/day by discontinuing diuretics or by decreasing intake. Ethanol use and hypercalcemia also contribute to increased excretion.
- Increased nighttime excretion suggests peripheral edema or late fluid ingestion.
- Comments help differentiate urge from stress incontinence.
- Be sure to reconsider causes of transient incontinence as you interpret the voiding record. Sedatives, diuretics, alpha-blockers, or anticholinergics may be confusing the picture.

Post-Void Residual (PVR) Measurement

The patient should void, without straining, and within 10 minutes the PVR should be measured either by straight catheterization or ultrasound. The patient should be instructed not to re-void before the measurement. If using catheterization to measure PVR, if the catheter is inserted correctly, there should be some urinary drainage. When this is complete, slowly withdraw the catheter, with the patient straining, to ensure complete collection.

Urodynamic Testing

After referral to urologist or urogynecology, the patient may undergo urodynamic testing. Urodynamic studies involve urethral catheterization of the patient for approximately one hour. During this time, fluid is instilled into the bladder and pressure measurements and x-rays are obtained which evaluate the storage function of the bladder. These tests can be used to assess objectively the underlying etiology of the bladder dysfunction.

Urodynamic tests include:

- 1. Cystometry: bladder pressure is measured during filling and emptying phases to evaluate detrusor function.
- 2. Uroflowmetry: measures urine flow rate during voiding to evaluate for emptying dysfunction.
- 3. Ureteral pressure profile: measures sphincter function.

Urodynamic testing is 91 percent sensitive and 51 percent specific in diagnosing pure stress incontinence and 73 percent sensitive and 55 percent specific in diagnosing urge incontinence. Therefore, urodynamic testing should not be used as a single diagnostic test to determine the cause of lower urinary tract disorders. After the patient has been fully evaluated with a history, examination, and laboratory testing, urodynamic testing may be done for the following indications:

- Uncertain diagnosis or mixed symptoms
- Failure to respond to intervention
- Proposed surgical intervention

Treatment of Urge Incontinence

Non-Pharmacologic Treatment

Adjust urine output	Urine output should be 1 to 1.5 liters/day (as measured by voiding record)
Urge suppression training	 Stay put when you get an urge-sit down when possible, or stand quietly. Squeeze pelvic floor muscles quickly several times (Kegel exercises), but do not relax fully between squeezes. Relax the rest of your body. Try to focus on another task to distract yourself.

	When the urge subsides, see how long you can wait before going to the toilet, then increase this time. Example: try to hold for 30 seconds the first time, then a minute the next time.
Bladder retraining	 Bladder training can take several weeks before effects are appreciated. Randomized controlled trials have indicated that bladder training can be more successful at decreasing incontinence than medications. After reviewing the voiding record, instruct patients to: Time voids to occur at regular intervals (6 to 8 times during the daytime), and gradually increase interval length by 30 to 60 minutes until able to void every 3 to 4 hours while awake. Concentrate on suppressing the urge to urinate between voids (see above).
Prompted voiding	 Should occur every 2 to 3 hours. Is effective in cognitively impaired individuals. Successful in individuals who do not void more often than 4 times in a 12-hour period and who are continent 75% of the time. Requires a great deal of effort on the part of the caregiver.

Pharmacologic Treatment

Drug	Dose	Comments
Oxybutynin (Ditropan®,	9	Also available in transdermal form. May take up to two weeks for full
Ditropan XL®)	or three times per day (tid). Extended release: 5 mg po once daily (qd). Titrate up to	effect to be appreciated. Adverse effects: dry mouth, constipation. May increase postvoid residual and lead to overflow incontinence.
Tolterodine (Detrol®, Detrol LA®)	1 to 2 mg po bid immediate	Causes dry mouth less frequently than oxybutynin.
Propantheline	15 to 30 mg po qd	Must be taken on an empty stomach.
Dicyclomine		Anticholinergic. Contraindicated in lactation and for patients with glaucoma.
Tricyclic Antidepressants	po four times a day (qid)	Not recommended for older patients- anticholinergic side effects and orthostatic hypotension may be limiting.

<u>Treatment of Overflow Incontinence</u>

Non-Pharmacologic Treatment

Medication changes	Discontinue medications that decrease detrusor contractility.
Clean catheterizations	As needed
Decrease post- void residual	 Encourage double voiding. (Instruct patient to attempt to void for I minute; dress and leave bathroom for <5 minutes and then try again. If no spontaneous voiding the second time, patient may apply pressure in suprapubic area to empty bladder.) Valsalva maneuver during voiding to decrease postvoid residual.

<u>Treatment of Stress Urinary Incontinence</u>

Non-Pharmacologic Treatment

Urethral compression	Have patient insert tampon (largest size) to compress urethra before exercising.
Pelvic muscle exercises (Kegel exercises)	 Increase strength in the muscles responsible for urethral closure. Studies in younger women show improvements in women who do exercises compared with no treatment. Involves contracting the muscles that close the urethra (same muscles that allow one to "stop" midstream while urinating) ten times, at least 3 times daily, holding contractions the count of 10. Patients should not practice Kegels by routinely starting and stopping flow of urine as this may disrupt micturition reflex. Contractions can be performed with assistance of vaginal cones, which are teardrop-shaped weights. The cone is placed in vagina and held in place while patient ambulates, for 15 to 20 minutes, about 3 to 5 times per week, using progressively heavier weights of the same size and shape. Biofeedback techniques may help patients identify the pelvic muscles to contract. This involves referral to a trained physical therapist who places pressure sensitive monitors in the vagina to measure muscle contraction and provide auditory or visual feedback information to improve exercise performance.
Pessary	 Most common type looks like a diaphragm, with holes in it to allow for passage of secretions. Usually fitted by gynecologist. Patients can remove by themselves at night or for cleaning (weekly cleaning is recommended). Alternatively, they can return every three months to gynecologist for removal and cleaning. For postmenopausal women, should be used with topical estrogen to avoid ulceration. May be left in during intercourse. Can be used as a diagnostic test to determine if corrective

surgery will be effective.

- Useful in following situations:
 - Slight bladder or uterine prolapse
 - Poor surgical risk or aversion to surgery
 - Future childbearing plans
 - Pregnancy
 - Anticipated poor surgical outcome (obesity or ongoing chronic cough--e.g., chronic obstructive pulmonary disease).

Surgical Treatment

Most effective treatment and should be strongly considered, even in elderly women, since it has an enormous impact on quality of life.

Bladder neck (retropubic) suspension procedures	 Pelvic fascia is lifted up and stabilized against the superior pubic ramus. Most effective type of surgery with 85 to 90% of women continent at one year and 70 to 90% at five years. Complications include urinary retention, hemorrhage, rectocele, and injury to bladder or ureter, infection, and detrusor overactivity.
Sling procedures	 Involve the use of autologous or synthetic material to support the urethra. Newer procedure, "tension free vaginal tape" (or TVT), can be done as an outpatient as a minimally invasive procedure. It is not an office procedure and is usually done under local, spinal, or general anesthesia. Cure rates range from 80 to 95% at 5 years. Similar rates of cure as bladder neck suspension surgery but voiding problems with the sling procedure. Complications include bladder laceration, urinary retention, sling erosion requiring revision, infection.
Minimally invasive needle vaginal suspensions	 Procedure involves supporting the bladder neck and proximal urethra using sutures to attach the fascia to the rectus fascia or pubic bone. Advantage over retropubic approach is that it is transvaginal, and therefore is associated with an easier post-operative recovery. Less effective than the retropubic suspension procedures. Cure rates are about 40 to 80%. Complications include de novo urge incontinence, bleeding, infection, entrapment of ilioinguinal nerves

Pharmacologic Treatment

Drug	Doco	Commonts
Diug	DOSE	Comments

Drug	Dose	Comments
Estrogen cream	1 g at bedtime (qhs) x 2 wks then 3x/week	Not recommended for women with absolute contraindication to estrogen
Estrogen-containing ring (Estring®, FemRing®)	Inserted by patient or in the office every 3 months	Acceptable for use in women with history of breast cancer because of minimal to no absorption systemically
Imipramine	10 to 25 mg po bid to qid	Useful in mixed incontinence, since has both alpha adrenergic effect on urethral closure and anticholinergic inhibition of detrusor
Pseudoephedrine	15 to 60 mg po tid	Over the counter (OTC). Alpha-adrenergic receptor effects on urethral closure. Not very effective, but useful in patients who are poor surgical risks.
Duloxetine (Not yet U.S. Food and Drug Administration [FDA] approved)	20 mg po qd	Selective serotonin and noradrenergic re- uptake inhibitor. Increases sphincter contraction via alpha agonist effects and 5-hydroxytryptamine-2 receptors.

CLINICAL ALGORITHM(S)

A clinical algorithm is provided in the original guideline document for the "Evaluation and Management of Urinary Incontinence".

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate assessment and management of urinary incontinence in women

POTENTIAL HARMS

- Adverse effects of oxybutynin (Ditropan®, Ditropan XL®) include dry mouth, constipation, and increase in postvoid residual leading to overflow incontinence.
- Tolterodine (Detrol®, Detrol LA®) may cause dry mouth.
- Tricyclic antidepressants may produce anticholinergic side effects and orthostatic hypotension.
- Complications of bladder neck (retropubic) suspension procedures include urinary retention, hemorrhage, rectocele, and injury to bladder or ureter, infection, and detrusor overactivity.

- Complications of sling procedures include bladder laceration, urinary retention, sling erosion requiring revision, and infection.
- Complications of minimally invasive needle vaginal suspensions include de novo urge incontinence, bleeding, infection, entrapment of ilioinguinal nerves.

CONTRAINDICATIONS

CONTRAINDICATIONS

- Dicyclomine is contraindicated in lactation and for patients with glaucoma.
- Estrogen cream is not recommended for women with absolute contraindication to estrogen.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This guideline is not intended to convey rigid standards, but instead should be tailored to the needs of the individual woman.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Clinical Algorithm

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Bengtson J, Chapin MD, Kohli N, Loughlin KR, Seligson J, Gharib S. Urinary incontinence: guide to diagnosis and management. Boston (MA): Brigham and Women's Hospital; 2004. 9 p. [16 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2004

GUIDELINE DEVELOPER(S)

Brigham and Women's Hospital (Boston) - Hospital/Medical Center

SOURCE(S) OF FUNDING

Brigham and Women's Hospital

GUI DELI NE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the <u>Brigham and Women's Hospital Web site</u>.

Print copies: Available from the Brigham and Women's Hospital, 75 Francis Street, Boston, Massachusetts 02115. Telephone: (800) BWH-9999.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on February 10, 2005. This summary was updated by ECRI on October 20, 2005, following the U.S. Food and Drug Administration advisory on Cymbalta (duloxetine hydrochloride).

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